

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket Nos. 78N-0021 and 78N-021P]

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AMB

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Certifier R. IEDESMA

**Skin Protectant Drug Products for Over-the-Counter Human Use; Final
Monograph; Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products. This amendment revises several of the indications for OTC skin protectant drug products to provide additional labeling claims that should not have been excluded from the final monograph (FM).

DATES: *Effective Date:* This rule is effective June 4, 2004.

Compliance Dates: The compliance date for products subject to part 347 (21 CFR part 347) with annual sales less than \$25,000 is June 6, 2005. The compliance date for all other products subject to part 347 is June 4, 2004. The compliance date for combination products containing skin protectant and sunscreen active ingredients in § 347.20(d) and for all products subject to part 352 ^{was} stayed until further notice ^{at} (See 68 FR 33362, June 4, 2003.) ^{re}

cd03134

per Kant
Giles, OFR
12-4-03

Comment Date: Submit written or electronic comments by [insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA issued a FM for OTC skin protectant drug products in part 347. Section 347.50(b)(2) of that FM includes the following indications for OTC skin protectant drug products:

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—*(i) The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked skin” (which may be followed by: “and lips”). This statement may be followed by the optional statement: “helps protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states “temporarily protects” (which may be followed by: “and helps relieve”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps protect lips from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

Shortly after FDA issued the FM, an industry national trade association submitted a petition (“The petition,” Ref. 1) requesting FDA to amend the FM

to permit the terms “helps prevent” and “chafed” in the indications in § 347.50(b)(2). The petition stated that FDA had included these terms in the indication in this section proposed in the tentative final monograph (TFM) (February 15, 1983, 48 FR 6820 at 6832), which stated: “Helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips.”

The petition noted that the preamble to the FM contained a discussion of a study using nonmonograph concentrations of glycerin (less than 20 percent) that were found to be inadequate to support the indication that had been proposed in the TFM (see 68 FR 33362 at 33367). The petition added that the FM did not provide adequate justification or discussion for the elimination of this claim for other skin protectant active ingredients. The petition stated that skin protectant products are selected frequently for their preventative as well as their protective benefits. The petition requested FDA to reconsider its decision not to include the terms “helps prevent” and “chafed” in the indications in § 347.50(b)(2) of the FM.

II. FDA’s Conclusions on the Petition

FDA has reevaluated the indications in § 347.50(b)(2) of the FM and concurs with the petition that these terms should have remained in these indications, as proposed in the TFM. However, because labeling space may be limited for some OTC skin protectant drug products and all manufacturers of these products may not wish to include this additional language in their products’ indications, FDA is including these additional terms as optional labeling in the indications in § 347.50(b)(2). Including these additional terms as labeling options will enable those manufacturers who wish to include these terms in product labeling to do so, but will not require all manufacturers of these products to have to include the terms if they do not wish to do so.

Accordingly, in this final rule, FDA is amending § 347.50(b)(2) to read as follows:

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—*(i) The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked skin” (optional: “and lips”). This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

FDA concludes that this revised labeling provides manufacturers a number of ways to state the indications for these OTC skin protectant drug products. Although not requested by the petition, FDA is also amending the indications in § 347.50(e)(1)(ii) [for products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10)] and (f)(1)(ii) [for products containing only cocoa butter, petrolatum, or white petrolatum, singly or in combination with each other, and marketed other than as a lip protectant]. FDA is amending these indications so that OTC skin protectant drug products labeled under these sections of the monograph can have comparable labeling to products labeled under § 347.50(b)(2). These amended sections read as follows:

(e)(1)(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] helps” (optional: “prevent and”) “protect” (optional: “and relieve”) “chapped lips”. If both optional terms are used, the

indication may be limited to: “Use [in bold type] helps prevent, protect, and relieve chapped lips”.

(f)(1)(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to “Use [in bold type] helps protect minor cuts and burns” or “Use [in bold type] helps” (optional: “prevent and”) “protect chapped skin” or “Use [in bold type] helps protect minor cuts and burns and” (optional: “prevent and protect”) “chapped skin”.

FDA also intends to amend one of the indications in § 352.52(f)(1)(ii) to add the optional “prevents” language to be comparable to the other labeling revisions being made above. FDA intends to propose that the revised indication state:

“For a lip protectant product, the heading and the indication required by § 201.66(c)(4) may be limited to: “Use [in bold type] helps protect against sunburn and” (optional: “prevent and protect”) “chapped lips”.

Because the final monograph for OTC sunscreen drug products in part 352 is currently stayed, FDA intends to propose this revision in an amendment of that monograph, in a future issue of the **Federal Register**.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to public interest. The labeling revisions represent a minor change to reinstate language that should not have been excluded from the FM, and to make other labeling in the FM consistent with the labeling proposed in the TFM. In addition, given the imminence of the current compliance dates (see DATES) for the FM, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. In accordance with 21 CFR 10.40(e)(1), FDA

is providing an opportunity for comment on whether the regulation should be modified or revoked.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any 1 year (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this final rule is to revise several monograph indications. These changes provide manufacturers of OTC skin protectant drug products additional options to state the uses in the labeling for their products.

All manufacturers of OTC skin protectant drug products will need to relabel their products as a result of the FM issued on June 4, 2003. Based on the amount of time it takes to relabel products (6 to 10 months, on average) FDA estimates that few, if any, manufacturers have relabeled their products as of the date of this technical amendment to the FM.

For the reasons stated in the previous paragraphs and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain

policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. PRC1.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 347 is amended as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

- 1. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

- 2. Section 347.50 is amended by revising paragraphs (b)(2), (e)(1)(ii), and (f)(1)(ii) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

* * * * *

(b) *Indications.* * * *

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—*(i) *The labeling states* (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked skin” (optional: “and lips”). This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked lips”. This statement may be followed by the optional statement: “helps” (optional: “prevent and”) “protect from the drying effects of wind and cold weather”. [If both statements are used, each is preceded by a bullet.]

* * * * *

(e) *Products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10) of this chapter.* * * *

(1) * * *

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] helps” (optional: “prevent and”) “protect” (optional: “and relieve”) “chapped lips”. If both optional terms are used, the indication may be limited to: “Use [in bold type] helps prevent, protect, and relieve chapped lips”.

* * * * *

(f) *Products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), singly or in combination with each other, and marketed other than as a lip protectant.* (1) * * *

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to “Use [in bold type] helps protect minor cuts and burns” or “Use [in bold type] helps” (optional: “prevent and”) “protect chapped skin” or “Use [in bold type] helps protect minor cuts and burns and” (optional: “prevent and protect”) “chapped skin”.

* * * * *



Dated: 12/1/03

cd03134

December 1, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

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